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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,312	03/25/2004	Takafumi Ueno	1011350-000332	5636

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EXAMINER	
FLICK, JASON E	

ART UNIT	PAPER NUMBER
3763	

NOTIFICATION DATE	DELIVERY MODE
12/04/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/808,312	UENO ET AL.	
	Examiner	Art Unit	
	JASON FLICK	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/30/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/28/2009 has been entered.

Response to Amendment

2. Examiner acknowledges the reply filed on 07/30/2009 in which claims 1, 11, 12, and 15 were amended. Currently, claims 1-7 and 9-17 are pending for examination in this application.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-7 and 9-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 7,322,960. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims contain similar structure and subject matter. The differences between the claims would be obvious to one of ordinary skill in the art.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al. (USPN 6,106,524), in view of Shapland et al. (WIPO 99/04851).

9. [Claims 1, 6, 7, 9, and 10] Eggers teaches a catheter to be percutaneously inserted into a living body lumen, said catheter (figure 8a, item 60) comprising: a sheath portion (figure 8a, item 67) having a lumen extending therein (figure 8a, item 62), an insertion member slidably disposed in said lumen of said sheath portion and having a distal end portion capable of protruding from a distal end portion of said sheath portion (figure 8a, item 61), an injection needle disposed at said distal end portion of said insertion member for injecting a therapeutic composition into a target tissue in a living body (figure 8b, item 130), and a first electrode disposed at said distal end portion of said insertion member and spaced from a bevel of said injection needle disposed at an outer circumferential surface of said distal end portion of said insertion member for measuring a cardiac action potential (figure 8a, item 65), and further comprising a second electrode disposed at said distal end portion of said sheath portion for measuring a cardiac action potential (figure 8a, item 66), wherein the electrodes are spaced apart from each other along the longitudinal direction of said insertion member (figure 8b). Eggers does not specifically disclose that an electrode is

fixed at the distal end portion of the insertion member. However, Shapland teaches a cardiac delivery catheter comprising an electrode which is fixed at a distal end portion of an insertion member and spaced from a bevel of an injection needle disposed at the distal end portion of an insertion member (page 7, lines 23-24 and 37-38; page 8, lines 1-20; figures 3 and 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Eggers, with the fixed electrode, taught by Shapland, in order to provide an alternate sensing location within the device and allow for the detection of the puncturing of target tissue.

10. [Claims 2 and 3] Eggers teaches the limitations of claim 1, upon which claims 2 and 3 depend. Eggers does not specifically disclose target cardiac tissue and therapeutic compositions of nucleic acid, proteins, or cells. However, Shapland teaches an intracardiac drug delivery catheter which discloses target tissue to be cardiac tissue (page 5, lines 7-21) and an injected therapeutic composition containing a nucleic acid, a protein, or cells (page 6, lines 23-32). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Eggers with the use of cardiac tissue as target tissue and the therapeutic composition, as taught by Shapland, in order to provide additional catheter capabilities allowing for alternative cardiac therapies.

11. [Claims 4 and 5] Eggers teaches the limitations of claim 1, upon which claims 4 and 5 depend. Eggers does not specifically disclose a through-hole located on the distal end portion of the sheath, which communicates with the lumen. However, Shapland teaches a cardiac delivery catheter comprising a plurality of through-holes

(outlet ports), located on the sheath portion of a catheter (figure 3, items 150), which communicates with the lumen. Additionally, Shapland discloses this plurality to be greater than a distance of 1mm from the end face of the distal portion of the sheath, along the longitudinal direction (page 8, lines 30-34). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Eggers with the through-hole structure taught by Shapland in order to provide the desired result of efficient drug delivery.

12. [Claim 11] Eggers and Shapland teach the limitations of claim 7, upon which claim 11 depends. Eggers and Shapland do not explicitly state that the electrode located on the distal portion of the insertion member is spaced greater than 1 mm from the distal end of the injection needle along the longitudinal direction. However, the spacing distance is a preferred design choice which, absent criticality, would be obvious to one of ordinary skill in the art.

13. Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haim et al. (USPN 6,309,370), in view of Eggers et al. (USPN 6,106,524), in further view of Shapland et al. (WIPO 99/04851).

14. [Claims 12, 13, and 15] Haim teaches a catheter (figure 1a, item 20) capable of being percutaneously inserted into a living body lumen, comprising: a sheath portion (figure 1a, item 26) containing a lumen, an insertion member (figure 1a, item 24) slidably disposed within the lumen of the sheath portion and having a distal end portion capable of protruding from a distal end portion of the sheath, an injection needle (figure 1a, item 24) located at the distal end of the insertion member for injecting a therapeutic

composition into a target tissue, and an electrode (column 12, lines 28-31)(figure 1a, items 38) located at the distal end of the catheter which is capable of measuring cardiac action potential. Additionally, Haim teaches a puncture detection unit (figure 2) to which a first and second electrode are connected (figure 1a, items 38), which is capable of detecting the puncture (position) of the injection needle based on a measured cardiac action potential (column 12, lines 26-31). Haim does not specifically disclose the first electrode is spaced from a bevel of an injection needle and a distal second electrode is located on the side of the proximal end of the catheter relative to the first electrode. However, Eggers teaches a catheter comprising a first electrode disposed at said distal end portion of said insertion member and spaced from a bevel of said injection needle disposed at an outer circumferential surface of said distal end portion of said insertion member for measuring a cardiac action potential (figure 8a, item 65), and further comprising a second electrode disposed at said distal end portion of said sheath portion for measuring a cardiac action potential (figure 8a, item 66), wherein the second electrode is disposed at a distal end portion of said catheter, and is located on the side of the proximal end of said catheter relative to said first electrode (figure 8b). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Haim with the location of the electrodes, as taught by Eggers, in order to provide increased flexibility in the detection of the position of the injection needle. In addition, Haim also discloses the insertion of the catheter, as well as the puncturing and injecting of a target tissue (column 9, lines 12-16). Additionally, Haim teaches that the injection of the therapeutic composition is

based on the measured cardiac action potential of the electrodes (column 6, lines 9-10; see also column 9, lines 39-44). Eggers and Haim do not specifically disclose that an electrode is fixed at the distal end portion of the insertion member. However, Shapland teaches a cardiac delivery catheter comprising an electrode which is fixed at a distal end portion of an insertion member and spaced from a bevel of an injection needle disposed at the distal end portion of an insertion member (page 7, lines 23-24 and 37-38; page 8, lines 1-20; figures 3 and 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Eggers and Haim, with the fixed electrode, taught by Shapland, in order to provide an alternate sensing location within the device and allow for the detection of the puncturing of target tissue.

15. [Claim 14] Haim, Eggers, and Shapland teach the limitations of claim 12, upon which claim 14 depends. Haim and Eggers are silent on a second electrode which is provided as a separate body independent from a catheter. However, Shapland discloses a second electrode which is a separate body independent from the catheter (page 8, lines 14-20; see also figure 4, items 162 and 164). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Haim and Eggers with the independent second electrode taught by Shapland in order to provide greater flexibility in the sensing capabilities of the catheter.

16. [Claims 16 and 17] Haim, Eggers, and Shapland teach the method steps of claim 15, upon which claims 16 and 17 depend. In addition, Haim teaches the method

steps of bringing the distal end portion of the sheath portion into contact with the target tissue, thereby measuring and detecting a change in cardiac action potentials with the electrodes (column 12, lines 28-31). Furthermore, Haim discloses the method steps of utilizing the insertion member distally of the sheath in order to protrude the injection needle from the sheath, thereby allowing the injection needle to puncture the target tissue (column 8, lines 23-25). Haim also teaches the injection needle is capable of administering the therapeutic composition into the target tissue based on whether or not a change in cardiac action potential is detected (column 6, lines 8-10).

Response to Arguments

17. Applicant's arguments with respect to claims 1-7 and 9-17 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON FLICK whose telephone number is (571)270-7024. The examiner can normally be reached on Monday through Thursday, 7:00am to 5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F./
Examiner, Art Unit 3763
11/12/2009

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763